#7 13
9/10/02

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office:

at Fax No.: 1-703-872-9306

On August 27, 2002

TOWNSEND and TOWNSEND and CREW LLP

By Rosemarie L. Celli

Rosemarie L. Celli, Reg. No. 42,397

PATENT

Attorney Docket No.: 15270J-005911US
ClientRef. No.: 209-US-NEW 6C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Sharon L. Turner
Dale B. Schenk	Art Unit: 1647
Application No.: 09/724,567	RESPONSE TO RESTRICTION REQUIREMENT
Filed: November 28, 2000	
For: PREVENTION AND TREATMENT OF AMYLOIDOGENIC DISEASE	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant files this response to the Restriction/Election of Species Requirement mailed March 27, 2002. A petition for an extend the time of response to the Office mailed March 27, 2002 from April 27, 2002 to August 27, 2002 is transmitted herewith. The paragraph numbering of the Restriction/Election of Species Requirement is used in responding to the Examiner's remarks.

1. Applicant elects Group II (claims 11-25).

9-10. Applicant traverses the Restriction Requirement, and provisionally elects synuclein of claim 13, and the synuclein-NAC fragment of claim 15. Applicant acknowledges the Examiner's requirement to elect a single amyloid component, *i.e.*, Applicant must elect one amyloid component, agent, and fibril component from each of

claims 13, and 15 of elected Group II. Applicant respectfully points out that claim 13 recites precursor proteins, and not amyloid components. Applicant's has provisional election of synuclein is based on the assumption that the Examiner intended to require that Applicant elect a precursor protein, not an amyloid component, from claim 13.

The Examiner has effectively required restriction between 15 species of generic claim 13, *i.e.*, Serum Amyloid A protein (ApoSSA), immunoglobulin light chain, immunoglobulin heavy chain, ApoAI, transthyretin, lysozyme, fibrogen α chain, gelsolin, cystatin C, Amyloid β protein precursor (β-APP), $Beta_2$ microglobulin, prion precursor protein (PrP), atrial natriuretic factor, keratin, islet amyloid polypeptide, a peptide hormone, and synuclein; including mutant proteins, protein fragments or peptides thereof. The Examiner has also effectively required restriction between 13 species of generic claim 15, *i.e.*, AA, AL, ATTR, AapoA1, Alys, Agel, Acys, Aβ, AB_2M, AScr, Acal, AIAPP and synuclein-NAC fragment.

The Examiner maintains that this requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. The only justification or statutory authority put forth by the Restriction Requirement for refusing to examine claim 13 is 35 U.S.C. § 121. However, there is nothing therein to excuse a refusal to examine an elected invention or a generic claim reading thereon.

As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be

> divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

Moreover, it has been held that an Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions. *See, In Re Weber, Soder and Boksay, Supra.* The courts have ruled that the statue authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II.* In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Instead of imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See,* 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied

with. *See,* the MPEP at 803.02. *See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application.

In the present case, the practical distinction between a restriction and election of species requirement is a simple one. If the Examiner agrees that claim 13 is patentable (as appears to be the case from the present office action), then claim 13 forms an allowable generic linking claim between the recited species, and the election of species requirement can be withdrawn as between these species (*see* MPEP 809.02(c)(B)(1)). Similarly, if the Examiner agrees that claim 15 is patentable (as appears to be the case from the present office action), then claim 15 forms an allowable generic linking claim between the recited species, and the election of species requirement can be withdrawn as between these species. It is believed that such would not impose a serious burden on the Examiner. By contrast, a restriction requirement would effectively require applicants to file a divisional application on claims whose patentability has already been established in the present case.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Rosemarie L. Celli

Rosemarie L. Celli
Reg. No. 42,397

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (650) 326-2400
Fax: (650) 326-2422
RLC:lah
PA 3246431 v1